



ABBOTT

Corporate Regulatory and Quality Science

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Richard M. Johnson
Director
Quality Center of Excellence for Drugs
D-03QA, AP6C-1
Telephone: (847) 938-1750

100 Abbott Park Road
Abbott Park, IL 60064-6091
Facsimile: (847) 938-4422
e-mail:
richard.m.johnson@abbott.com

September 1, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

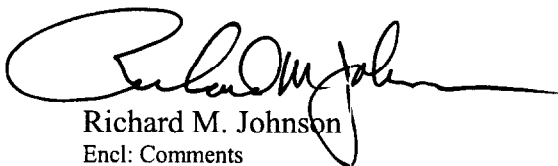
Ref: Docket No 2005D-0174 – Draft Guidance on Expiration Dating of Unit-Dose Repackaged Drugs

To Whom it May Concern:

Abbott is very pleased to have the opportunity to provide comments on the Draft Guidance on Expiration Dating of Unit-Dose Repackaged Drugs published on May 31, 2005 in the *Federal Register*.

We thank the Food and Drug Administration for your consideration of our comments. Should you have any questions, please contact Kathy Wessberg (tel: 847-938-1264, e-mail: kathy.wessberg@abbott.com).

Sincerely,



Richard M. Johnson
Encl: Comments

2005D-0174

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ABBOTT COMMENTS TO FDA ON

Docket No. 2005D-0174

COMMENTS

Specific Comments:

III. Discussion:

Proposed change:

Add to the paragraph after point #4 that if the repackager uses a container / closure system that is not equivalent to the manufacturer's market package that the repackager bears responsibility for determining stability of the new container/closure system.

Change text as highlight in bold:

At the end of the paragraph in point #4 add:

"If the repackager does not use a container closure system equivalent to the manufacturer's market package, then the repackager must generate stability data for the drug product in the new container-closure system to justify the expiration date or BUD used."

Reason:

Statement should be added to be consistent with USP <1178> Good Repackaging Practices and FDA Guidance for Industry: Container Closure Systems for Packaging Human Drugs and Biologics Chemistry, Manufacturing and Controls Documentation which states: "A repackager is a firm that buys drug product from the drug product manufacturer or distributor and repackages it for sale under a label different from that of the manufacturer. The repackager is responsible for ensuring the quality and stability of the repackaged drug product."